



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Cresemba belongs to a class of drugs called azole antifungal agents, which target the cell membrane of a fungus. Cresemba is used to treat adults with invasive aspergillosis and invasive mucormycosis. Aspergillosis is a fungal infection caused by *Aspergillus* species, and mucormycosis is caused by the *Mucorales* fungi. These infections occur most often in people with weakened immune systems (1).

### **Regulatory Status**

FDA-approved indications: Cresemba is an azole antifungal indicated for use in the treatment of invasive aspergillosis and invasive mucormycosis as follows (1):

- Cresemba for injection: adults and pediatric patients 1 year of age and older
- Cresemba capsules: adults and pediatric patients 6 years of age and older who weigh 16 kilograms (kg) and greater

Cresemba is contraindicated in patients with familial short QT syndrome. Cresemba is also contraindicated when co-administered with strong CYP3A4 inhibitors or strong CYP3A4 inducers (1).

Specimens for fungal culture and other relevant laboratory studies (including histopathology) to isolate and identify causative organism(s) should be obtained prior to initiating antifungal therapy (1).

Hepatic adverse drug reactions (e.g., elevations in alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin) have been reported in clinical trials. Evaluate liver-related laboratory tests at the start and during the course of Cresemba therapy. Monitor patients who develop abnormal liver-related laboratory tests during Cresemba therapy for the development of more severe hepatic injury. Cresemba has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and should be used in these patients only when the benefits outweigh the risks (1).

The safety and efficacy of Cresemba in patients less than 1 year of age have not been established (1).

### **Summary**

Cresemba is used to treat adults with invasive aspergillosis and invasive mucormycosis. Aspergillosis



**BlueCross.  
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**CRESEMBA**  
(isavuconazonium)

is a fungal infection caused by *Aspergillus* species, and mucormycosis is caused by the Mucorales fungi. These infections occur most often in people with weakened immune systems. The safety and efficacy of Cresemba in patients less than 1 year of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cresemba while maintaining optimal therapeutic outcomes.

**References**

1. Cresemba [package insert]. Northbrook, IL; Astellas Pharma US, Inc. December 2023.